

Tab 27

From: Doug Kalman MS, RD [dknole@hotmail.com]
Sent: Thursday, April 26, 2001 11:46 AM
To: BobC@prosourceonline.com
Subject: RE: reply Xenadrine safety study

Bob,

there is a placebo group. I will rework the framework of the hypothesis (a work in progress) and the proposal to include pre and post echocardiograms..

You will receive it shortly.

DK

-----Original Message Follows-----

From: BobC@prosourceonline.com
To: dknole@hotmail.com
Subject: RE: reply Xenadrine safety study
Date: Thu, 26 Apr 2001 11:25:20 -0400

Doug,

Let us know what the additional cost would be.

As for your latest study proposal, I don't see any placebo group. Also in the hypothesis you write "the continual stimulation of norepinephrine/epinephrine can lead to adverse effects...". This is inconsistent with everything we've seen and I don't think it's a good thing to say, particularly considering the fact that this is only a two week study and would not conclusively prove otherwise in such a short time frame.

I would suggest that you rework that section of the hypothesis. There are many ambulance chasing lawyers out there that would hang on to sentences (such as that) and get mileage by using them completely out of context. Lastly, is it necessary to call this a "pilot" study? The primary purpose of this study is to have more support to show the safety of Xenadrine and we wouldn't want to give the lawyers an angle to discredit the conclusions of the study.

Bob

-----Original Message-----

From: Doug Kalman MS, RD [SMTP:dknole@hotmail.com]
Sent: Thursday, April 26, 2001 10:16 AM
To: tzphd@hotmail.com
Cc: bobc@prosourceonline.com
Subject: Re: reply Xenadrine safety study

A pre and post echo? Those are expensive. I do not mind doing it--
however the cost would have to be adjusted appropriately.

We would be happy to do it.

DK

-----Original Message Follows-----

From: "Tim Ziegenfuss" <tzphd@hotmail.com>

To: dknole@hotmail.com, BobC@prosourceonline.com
CC: kpconklin@aol.com
Subject: Re: reply Xenadrine safety study
Date: Thu, 26 Apr 2001 10:05:44 -0400

Doug,

Since Dr. Feldman is a co-investigator, what is the chance that measures of cardiovascular stress might also be assessed? For example, resting cardiac output, stroke volume, ejection fraction, etc.

Your thoughts?

TZ

-----Original Message Follows-----

From: "Doug Kalman MS, RD" <dknole@hotmail.com>
To: BobC@prosourceonline.com
CC: tzphd@hotmail.com
Subject: reply Xenadrine safety study
Date: Wed, 25 Apr 2001 16:10:51 -0400

Bob,

Tim and spoke at length and believe that in the study that we are currently discussing by adding RQ/RER/RMR testing-- essentially what would be an expedient study would become a labor and time intensive study. It may be best for Cytodyne to do a short term metabolic RQ/RER/RMR study with Tim at Kent State and the safety study with Miami Research Associates.

We agree to add a placebo group and do it at a 2:1 ratio of treatment versus placebo. To insure the sanctity of the study the bottles must be serially labeled.

If you want, we can, according to the following studies add predicted BMR through various equations and/or BIA. Thus indirectly, since BMR is based on fat free mass we can see if there are any changes in basal metabolism. Nonetheless, I will get you an update proposal today.

Cunningham JJ. A reanalysis of the factors influencing basal metabolic rate in normal adults. Amer J Clin Nutr 1980;33:2372-2374. EQUATION FOR MALES BMR
$$= 500 + (22) \text{LBM IN KG.}$$

Allen C, Don Michael TC, Antonescu A, et al. Utilization of bioelectric impedance to predict energy expenditure in obese subjects. Validation by measurement of $\dot{V}O_2$ during exercise. Obesity Research 2000;8(1):PB79
EQUATION is $14 \times \text{LBM in pounds.}$

DeLorenzo A, Bertini I, Candeloro N, et al. A new predictive equation to calculate resting metabolic rate in athletes. J Sports Med Phys tness 1999;39:213-219.

EQUATION RMR = -857 + 9(weight in kg) + 11.7(Height in cm).

Doug

-----Original Message Follows-----

From: BobC@prosourceonline.com
To: dknole@hotmail.com
Subject: RE: Xenadrine attachment (2) proposal and contract
Date: Wed, 25 Apr 2001 14:14:01 -0400

Doug,

Ideally, we would like to have this study set up to test and document both the safety and efficacy. Can you work into the proposal testing for the RQ, RER, and BMR as per the earlier proposal? If you could work this in for a reasonable fee, it would give us the opportunity to get two birds with one stone.

Also, we ran your proposal by Tim Z. and he feels that it should also include a placebo group and be double-blinded. Perhaps we can do 20 experimental and 10 placebo.

Let me know your thoughts as soon as possible, as we would like to get something underway in time to take advantage of the upcoming publication opportunities which you had mentioned.

Bob

-----Original Message-----

From: Doug Kalman MS, RD [SMTP:dknole@hotmail.com]
Sent: Thursday, April 19, 2001 2:37 PM
To: kpconklin@aol.com
Cc: BobC@prosourceonline.com
Subject: Xenadrine attachment (2) proposal and contract

Kelly,

see attached, per your request.

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